STANDARD OPERATING PROCEDURE FOR THE USE OF TRANSLATION SERVICES FOR RESEARCH STUDIES UNDERTAKEN BY NHS FIFE

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1. PURPOSE

This document describes the procedure for utilising interpreter and translation services in clinical research studies undertaken by NHS Fife.

It is the responsibility of all researchers using this SOP to ensure they are using the latest version of it. The latest version is available via the Research & Development (R&D) pages on the NHS Fife Intranet (www.nhsfife.org/research). For guidance, contact the R&D Department via fife-uhb.randd@nhs.net.

2. APPLICABILITY

This SOP applies to all staff working under NHS Fife R&D policies, but can be used by any NHS Fife employees involved in research where it is applicable. Where the Boards services are provided by external contractors, sub-contractors, agencies, temporary workers or third parties on the basis of a specification set by the Board, these parties are reponsibile for adhering to the Boards Dignity & Respect Policy whilst providing services on behalf of NHS Fife.

3. POLICY

3.1 The Medicines for Human Use (Clinical Trials) Regulations 2004 which governs the conduct of CTIMPs requires that a patient must give informed consent to participate in a clinical trial. That means that the subject (or person with parental responsibility or legal representative) has been informed of the nature, significance, implications and risks of the trial. This should be communicated in a way as to be understandable to the subject or the subjects legally acceptable representative.

3.2 It is the responsibility of the Sponsor to assess their intended patient group and, if verbal translation is needed, whether it should be via a hospital interpreter or a independent interpreter and to decide if telephone translation services are acceptable. This should be clearly written in the study protocol. If this is not the case the trial centre/sponsor must be contacted directly to confirm if patients requiring translation services are eligible for the trial.

3.3 The CI and Sponsor for each study will be responsible for determining if translated written material is to be provided to participants, and if they will be provided by the sponsor, or translated locally, and what arrangements are in place to confirm the accuracy of the translation.

3.4 It is the responsibility of the study Sponsor/CI to decide if translation services will be required throughout the entirety of the study, based on risk, the complexity of the study procedures and the language skills of the individual. This should be discussed prior to the patient attending for their first study visit and clearly documented in the medical and research notes.

3.5 If translations services are deemed necessary and the sponsor is not willing to meet the cost, the R&D Assistant Director will make a decision as to the appropriateness of R&D covering the cost.

3.6 It is the responsibility of all staff to:

- Identify and record individual need: finding out if someone has any information or communication needs and recording them in the medical and research notes if they do.
- Share and check individual need: passing on information about an individual's needs to people who are looking after them. It also means checking their needs are met to the best of our capability, each time the individual comes to use the service.
- Take action to meet their needs: making sure that the person's needs are met, for example sending them information in the right format or providing the communication support they need (i.e. arranging for translation/interpretation services).

3.7 NHS Fife provides interpreting and translation services for patients who:

- Do not have English as their first language
- Have a hearing impairment
- Have sight impairment
- Are registered Deafblind

The need for interpreting and translation services will be assessed on individual need and patient capability.

4. PROCEDURE

4.1 Once a study participant requiring communication support has been identified by the study team and has agreed to participate in a research study, the sponsor must be made aware of the need for any interpreting services.

4.2 It is not appropriate for family members to act as interpreters and all interpretation of research information/documentation must be translated by an official NHS Translation service.

4.3 Some study Sponsors will provide a Patient Information Sheet (PIS) and Consent Form in an appropriate language, therefore these should be utilised wherever possible. If available, a copy of the translated PIS and Consent form must be given to the patient, and a further copy filed in the patient's medical notes with a File Note explaining the reason for the additional language PIS/Consent Form. A copy in English must also be filed in the medical notes.

If alternative language documentation is not available the information exchanged between the patient, the interpreter and the research staff should be clearly documented in the medical notes. This should include the nature and purpose of the study, the risks and benefits of the trial, the rights of the patient to withdraw, any questions asked and the response to them.

4.4 Interpreter services should be arranged in advance of the patients visit by contacting the NHS Fife Equality and Human Rights Department at:

- Phone - 01592 729130 (external) or 29130 (internal)
- Email - fife-UHB.EqualityandHumanRights@nhs.net

4.5 For all patients requiring interpretation services, an alert must be put on Trakcare detailing the translation requirements, if not already recorded on Trakcare. This will highlight to all staff that the patient is not an English speaking patient or has hearing or sight impairment and may require translation services.

4.6 Details of the interaction between the translation services and the patient, including the name of the official translator, must be documented in the research notes and the nursing/medical notes at each visit. This will include translation of Pharmacy dispensing advice of study medications.

4.7 Every effort must be made by staff to provide continuity of care and arrange for the same interpreter for each study visit.

5. ASSOCIATED DOCUMENTS & REFERENCES

World Medical Association Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects.
(https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/)

Medicines for Human Use (Clinical Trials) Regulations 2004.
(http://www.legislation.gov.uk/uksi/2004/1031/contents/made)
It is assumed that by referencing the principal regulations, all subsequent amendments made to the principal regulations are included in this citation.

UK Policy Framework for Health and Social Care Research
https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/.

SOP14 (Fife) – Informed Consent

6. ABBREVIATIONS

CI	Chief Investigator
CTIMP	Clinical Trials of Investigational Products
PIS	Patient Information Sheet
R&D	Research and Development
SOP	Standard Operating Procedure

7. DOCUMENT HISTORY

Version Number:	Edited by (job title):	Effective Date:	Details of Revisions Made:
1	Karen Gray Lead Nurse, R&D	21/11/2018	N/A – new SOP

8. APPROVAL

APPROVED BY	Date
Professor Alex Baldacchino, Research & Development Director, NHS Fife Signature: 	21/11/2018